

CLAIMS

It is claimed:

1. A method for preventing or ameliorating a symptom of ethanol intolerance in a subject with reduced or absent aldehyde dehydrogenase subtype 2 (ALDH2) activity comprising orally administering to the subject about 1 mg to about 4 mg 4-methylpyrazole (4-MP) per kilogram of the subject's body mass.
2. The method of Claim 1, wherein 4-MP is administered in a free base form.
3. The method of Claim 1, wherein 4-MP is administered in a physiologically acceptable salt form.
4. The method of Claim 1, wherein 4 -MP is orally administered before the subject consumes ethanol.
5. The method of Claim 4, wherein 4-MP is orally administered about one hour to about fifteen minutes before the subject consumes ethanol.
6. The method of Claim 1, wherein 4 -MP is orally administered concurrently with the subject's consumption of ethanol or after the subject has consumed ethanol.
7. The method of Claim 1, wherein the percent reduction in the subject's ethanol elimination rate is no more than about 10% in comparison to the ethanol elimination rate of a subject not administered 4-MP.
8. A method of preventing or reducing a symptom associated with acetaldehyde accumulation accompanying ethanol consumption in a subject with reduced or absent aldehyde dehydrogenase subtype 2 (ALDH2) activity comprising administering an effective amount of 4-MP that reduces acetaldehyde accumulation by about 50% to about 60% as compared to a subject not administered 4-MP.

9. The method of Claim 8, wherein the subject with reduced or absent ALDH2 activity exhibits a percent reduction in ethanol elimination rate that is no more than about 10% in comparison to the ethanol elimination rate of a subject not administered 4-MP.
10. A method of ameliorating a symptom of acetaldehyde accumulation accompanying ethanol consumption in a subject with reduced or absent aldehyde dehydrogenase subtype 2 (ALDH2) activity comprising administering an amount of 4-MP or a physiologically acceptable salt of 4-MP effective to reduce or inhibit ethanol-oxidizing activity of alcohol dehydrogenase in the subject.
11. The method of Claim 8 or 10, wherein a symptom of acetaldehyde accumulation in the subject with reduced or absent ALDH2 activity is selected from the group consisting of flushing, elevated heart rate, palpitations, hypotension, nausea, dizziness, and headache.
12. The method of Claim 10 wherein an effective amount of a hydrochloride salt of 4-MP is administered.
13. The method of Claim 10 wherein about 1 milligram to about 4 milligrams of 4-MP per kilogram of subject body mass is administered.
14. An article of manufacture comprising packaging material, and a composition comprising 4-methylpyrazole (4-MP), or a physiologically acceptable salt thereof, and a physiologically acceptable excipient, suitable for oral administration to a subject.
15. The article of manufacture of Claim 14 wherein the form of the composition is liquid.
16. The article of manufacture of Claim 14 wherein the form of the composition is a tablet.
17. The article of manufacture of Claim 16 wherein the tablet comprises about 85 milligrams of 4-MP.

18. The article of manufacture of Claim 16, further comprising printed instructions regarding the use or administration of the composition.

19. The article of manufacture of Claim 18 wherein the printed instructions suggest a dosing regimen for the prevention or amelioration of a symptom of acetaldehyde accumulation accompanying ethanol consumption in a subject.

20. The article of manufacture of Claim 19 wherein the printed instructions direct the subject to orally ingest a predetermined number of tablets according to the following table:

| <u>Subject's body mass</u> | <u>No. of tablets to ingest</u> |
|----------------------------|---------------------------------|
| 36-46 kg | 1 |
| 46-66 kg | 2 |
| 66-86 kg | 3 |
| 86-106 kg | 4 |
| 106-126 kg | 5. |